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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,380	09/29/2000	Andre T. Baron	99-057	1919

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/676,380	BARON ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *15 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☒ Claim(s) *18-31* is/are allowed.

6)☒ Claim(s) *9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed 15 December 2006 is acknowledged. Claim 9 is amended. Claims 24-31 are new. Claims 1-9 are withdrawn. Claims 9-31 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112, first paragraph

The rejection of claims 9-17 under 35 U.S.C. 112, first paragraph for scope of enablement is withdrawn in response to Applicants amendment of claim 9. Specifically, the unexpected result of a decrease in EGFR concentration and its correlation to the presence of carcinoma (any carcinoma) in a patient is no longer an element of the claim, thus claim 9 now encompasses a general assay for detection of EGFR for which there is a high level of skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-17 are rejected under 35 U.S.C. 103(a) is as being unpatentable over Harvey et al. (U.S patent 5,674,753, 1997), Partanen et al. (J. Occup. Med., 1994; 36: 1324-1328) or Witters et al. (Clin. Cancer Res., 1995; 1: 551-557) in view of Graus-Porta et al. (EMBO J. 1997; 16: 1647-1655) or Olayioye et al. (J Biol Chem. 1999; 274: 17209-17218), and further in view of Johansen et al. (WO 94/11734, 1994). Note that this is the same rejection that was made in the Office action mailed 7 May 2002 and thus the original rejection is herein reinstated. Further comment by the Examiner is made on this rejection was made in the Office actions mailed 14 January 2003 and 21 December 2005. This rejection was withdrawn in the Office action 19 June 2006, because the Applicants had incorporated all the claim limitations from claim 18 into claim 9, however, the current amendment leaves out step f), and without this step, claim 9 and its dependents are encompassed by a method of measuring EGFR and comparing to normal values, i.e., the unexpected element of correlating a decrease in receptor levels is no longer an element of the claim, thus reinstatement of this rejection was necessitated by amendment.

The basis of the original rejection can be found in the Office action mailed 7 2002, with additional issues addressed in the Office action mailed 14 January 2003, which are herein incorporated by reference. To further explain, Harvey et al. teach detection of EGFR in serum, blood. Harvey does et al. do not detection in urine. Partanen et al. and Witters et al. teach the detection of soluble forms of the EGF receptor in serum (Partanen et al.) or urine (Witters et al.). Partanen, Witters and Harvey and their respective colleagues do not teach the specific antibodies or the assay technique recited by Applicants. Graus-Porta et al. (see Materials and Methods, p. 1653) and Olayioye et al. (see Materials and Methods, p. 17210) teach the antibodies recited by Applicants for detection of the EGF receptor, these antibodies are against the extracellular region and thus detect both soluble and cell-surface forms of the receptor. Neither Graus-Porta et al. nor Olayioye et al. teach the assay method as recited by Applicants. Johansen et al. teaches an assay method in which one detecting reagent is immobilized using paramagnetic particles, the second is labeled with biotin, and the complex is detected with acridinium bound to streptavidin (see p. 1, lines 6-14). Although Johansen et al. does not teach direct labeling with acridinium, such a modification would be obvious to one of ordinary skill in the antibody art as a substitute for binding of the avidin-linked complex to the biotinylated molecule because it is a variation on the label, and does not change the outcome of the assay. It would have been obvious to one of ordinary skill in the art to modify the method of Harvey et al., Partanen and Witters to use the assay technique taught by Johansen et al. to detect soluble EGF receptors using the antibodies taught by Graus-Porta et al. and Olayioye et

al. for the following reasons. First, one of ordinary skill in the art would be motivated to detect EGFR, because Partanen et al., Witters et al., and Harvey et al. all teach that such detection is useful and detection of EGF is linked with certain types of cancer. Second, Graus-Porta et al. and Olayioye et al. teach antibodies that detect the extracellular region of the receptor, which would be useful for detecting soluble receptors. Third, Johansen et al. teaches an improved method of detection using labeled antibodies. Thus one of ordinary skill would know that the detection of soluble EGF receptors was useful, that mAbs R. 1 and 528 could be used to detect soluble EGF receptors, and that the assay of Johansen et al. would be expected to be useful for such detection. The skill in the antibody art is high, and one of ordinary skill in the art could expect success employing the methods outlined in the prior art, thus the claims do not teach anything non-obvious over the prior art.

Conclusion

Claims 9-17 are rejected. Claims 18-31 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

Christina Borgeest, Ph.D.

ELIZABETH KEMMERER
PRIMARY EXAMINER